REMARKS

In the office action mailed 08 August 2007, claims 1-23 have been rejected under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a). As set forth more fully below, Applicant traverses the rejections.

Claim rejections: 35 USC § 102

At paragraph 4 et seq. of the detailed action the Examiner has rejected claims 1-2, 4, 12, 14, and 21-22 under 35 U.S.C. § 102(e) as being anticipated by Paterson (Pub. No. US2002/0193979).

In order to anticipate a claim, a single prior art reference must disclose each of the limitations of the claim. See, e.g., *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 47 USPQ.2d 1516 (Fed. Cir. 1998), *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ.2d 1051 (Fed. Cir. 1987), MPEP 2131. As set forth more fully below, the cited prior art reference fails to disclose one or more of the limitations of the claims as currently presented.

Paterson

Paterson discloses an apparatus and method for validating a computer model of a real-world system - "a process of establishing a certain level of confidence that a computer model will behave as expected when compared to the actual, predicted, or desired data for a modeled system" (Paterson at para. 4). In Paterson the real-world systems, such as biological systems, already exist and are merely to be studied and not to be modified or made to conform to any standards or requirements. (Paterson at para. 27). There is no opportunity to specify validation requirements for the real-world system, nor is there an opportunity to later alter the real-world system to improve its conformance to validation requirements. The only measurements in Paterson are made to assure the computer model's similarity to the real-world system.

To measure the model's similarity, Paterson discloses determining a stimulus-response test and then having the computer-readable medium in Paterson simply "apply the stimulus-response test to the set of configurations to produce a simulated response" (Paterson Abstract). Knowing the real-world system's response, the model's response is compared thereto to determine whether a useful model has been found - thus validating the computer model.

Paterson does not contemplate validating a computer system and setting requirements for that validation, generating a validation plan for a computer system, determining a computing environment, generating a plurality of tests, presenting tests to a user, receiving responses from the user as to a status of the tests, and generating and presenting validation reports and messages.

Claim 1

At paragraph 5 of the detailed action, the Examiner rejects claim 1 as being anticipated by Paterson. Applicant respectfully submits that Paterson fails to either disclose or suggest, *inter alia*, a computer-implemented method of validating a computer system. For example, Paterson fails to disclose at least validating a *computer system*, receiving a plurality of validation requirements, generating a validation plan for a computer system based on received data, determining a computing environment, generating a plurality of tests, presenting tests to a user, receiving responses from the user as to a status of the tests, and generating and presenting validation reports and messages.

As described herein, and in particular above, Paterson discloses an apparatus and method for validating a computer model of a real-world system. The computer model in Paterson "can be a mathematical model that represents a set of dynamic processes associated with a modeled system using a set of mathematical relations...[that] typically includes one or more variables, each of which represents a

quantity for which the behavior (e.g., time evolution) can be simulated by the computer model". The computer model is not real and is intended to be an abstract representation of a real system. Further, the real-world systems in Paterson are not validated and are not intended for validation - they are intended for modeling and include biological systems and chemical systems.

A computer system, as disclosed and claimed by the Applicant, is real and tangible. As described in the present application, it may include a workstation and other equipment configured to perform various functions, such as scales and related communication and input/output devices to weigh pharmaceutical ingredients. It is of no consequence or use to model the computer system; it requires validation according to the present invention and does not relate to Paterson.

With respect to receiving data representative of a plurality of requirements for validating said computer system, the Examiner cites Paterson at page 2, section [0028]. The Applicant assumes that the Examiner is equating the one or more stimulus-response tests to the requirements for validating. However, the stimulus-response tests are simply data points to be applied as stimuli to the computer model, with expected results based on how the real-world system reacts. Further, the stimulus-response tests relate only to operation of the system and not designing or building the system. As clearly exemplified in the present claims (at least claims 1 and 2) and described in the specification, validation requirements are more than data points. Validation requirements may be holistic or heuristic, and may include, for example, objectives such as test objectives and requirements for building the system that is also to be tested. Validation requirements may include one or more qualifications, which may include, or lead to, at least one of requirements, test objectives and test instructions. They allow generation of a validation plan and a plurality of tests for the computer system, and determination of an appropriate computing environment. The data point stimulus-

response tests in Paterson are not validation requirements, and are not disclosed to be used for their purposes.

With respect to generating a validation plan, the Examiner cites Paterson at page 2, section [0028]. The Applicant respectfully submits that Paterson at page 2, section [0028] does not disclose generation of a validation plan. The "one or more stimulus-response tests are applied to the computer model" with no further thought given to such application. Hence there is no generation of a validation plan.

With respect to determining a computing environment appropriate to said computer system based on said received data, the Examiner cites Paterson at page 2, section [0028]. Applicant respectfully submits that Paterson does not disclose, in the cited section or elsewhere, selection of such a computing environment. Paterson's validation of a computer model may occur on a computer, but there is no suggestion of selecting the computer based on the real-world model, the computer model, or the validation structure.

With respect to generating a plurality of tests for the computer system to be performed during an implementation of the validation plan, the Examiner cites Paterson at page 2, section [0029]. Applicant respectfully submits that Paterson does not disclose, in the cited section or elsewhere, generating tests. Paterson simply "defines a validation structure" based on known real-world stimuli-responses (Paterson at page 2, section [0028]) and applies them to the computer model. Paterson does not disclose *generating* tests and has no validation plan for furing which any generated tests could be performed.

With respect to presenting said tests to a user as part of the implementation of a validation plan, the Examiner cites Paterson at page 2, section [0029]. Paterson discloses presenting the stimulus responses to the user, but does not disclose presenting the tests themselves or providing users an opportunity to review the tests

prior to implementation. After the stimulus-response tests have been received, the process continues without the user's input or awareness until results of testing are presented to them.

With respect to receiving responses from said user as to a status of said tests, the Examiner cites Paterson at page 2, section [0029]. Applicant respectfully submits that Paterson does not disclose the user providing a status of a test. The user does not indicate, for example, whether the test has been completed, was performed by them, was accepted or has been deemed unimportant. As stated herein, once the stimulus-response tests have been received the user does nothing until viewing results. They do not provide any status of any test. Paterson may disclose a user indicating whether the result of a test is acceptable to them, but does not disclose receiving responses as to a status of a test.

Applicant respectfully submits that at least these limitations of claim 1 are not disclosed in Paterson and hence claim 1 is not anticipated by Paterson. As paragraph 5 of the detailed action, the Examiner rejects claims 2, 12 and 22 as being anticipated by Paterson.

<u>Claims 2, 12 and 22</u>

At paragraph 5 of the detailed action, the Examiner rejects claims 2, 12 and 22 as being anticipated by Paterson. Applicant respectfully submits that Paterson fails to either disclose or suggest, *inter alia*, a computer-implemented method, apparatus and readable media for validating a computer system. For example, Paterson fails to disclose at least validating a *computer system*, receiving a plurality of validation requirements for validating a computer system.

Applicant submits, as more fully described herein, that the computer model in Paterson is clearly not a computer system and hence Paterson does not disclose validating a computer system.

With respect to receiving a plurality of validation requirements, the Examiner cites Paterson at page 2, section [0028]. As described herein, and for example with respect to claim 1 above, Paterson fails to disclose validation requirements, only disclosing simple data points as stimulus-response tests. Further, and as described herein, the stimulus-response tests in Paterson relate to validating a computer model and not a computer system.

Claims 4 and 14

At paragraph 5 of the detailed action, the Examiner rejects claims 4 and 14 as being anticipated by Paterson. As with all dependent claims, if the base claims are patentable, then the dependent claims are also patentable. Applicant respectfully submits that the base claims (claims 2 and 12 respectively) are patentable, as per Applicant's submissions herein, and therefore so are claims 4 and 14.

Claims 11 and 21

At paragraph 5 of the detailed action, the Examiner rejects claims 11 and 21 as being anticipated by Paterson. As with all dependent claims, if the base claims are patentable, then the dependent claims are also patentable. Applicant respectfully submits that the base claims (claims 2 and 12 respectively) are patentable, as per Applicant's submissions herein, and therefore so are claims 4 and 14.

Claim rejections: 35 USC § 103

At paragraph 7 et seq. of the detailed action the Examiner has rejected claims 3, 5-10, 13, 15-20 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Paterson (Pub. No. US2002/0193979) in view of Brinkman et al. (Pub No. 2005/0065818).

To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, in the references or in the knowledge generally available to someone of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Finally, there must be a reasonable expectation of success. *KSR International v. Teleflex*, U.S. Supreme Court No. 04-1350 (2007), MPEP 706.02(j).

<u>Suggestion Or Motivation To Modify Or Combine</u>

As previously stated in Applicant's previous Office Action response, Brinkman discloses an "integrated member decision support system [that] provides a method for corporations, insurance carriers, health maintenance organizations, physicians and physician groups, or other clients to efficiently provide medical, pharmaceutical, and health benefit advice and information for an enrolled population." (Abstract) A person in the enrolled population must be validated before using a feature of the system to address a symptom they have or a concern they have. The system may use previously stored information about the person from completed tests or prior advice to address the symptom or concern.

As described herein, Paterson discloses an apparatus and method for validating a computer model of a real-world system ("computer system" of the present invention) - "a process of establishing a certain level of confidence that a computer model will behave as expected when compared to the actual, predicted, or desired data for a modeled system" (Paterson at para. 4).

Applicant submits there is no suggestion or motivation to combine the references and further that it is illogical to do so. Paterson discloses validating a computer model of a real-world system; allowing the model to be used instead of the real-world system itself. This involves building a computer model and using stimulus-response results

from the real-world system to validate the model. The real-world systems in Paterson modeled, for example, to facilitate safe and easy testing and to allow extrapolation of results. The system in Brinkman suffers from no disadvantage that would cause someone to create a computer model of it; there is simply no benefit in building and validating a computer model of the system in Brinkman. Further, any stimulus-response data from the real-world system in Brinkman would be as easily applied to the real-world system as to any model of Brinkman. Creating and validating a computer model of Brinkman simply does not make sense.

For at least these reasons, Applicant submits that there is no suggestion or motivation, in the references or in the knowledge generally available to someone of ordinary skill in the art, to modify the reference or to combine reference teachings. In fact, Applicant submits that a person of ordinary skill in the art would be taught away from combining these references given the purposes of both references, and especially the purposes of Paterson.

Teaching Or Suggesting All Of The Claim Limitations

Applicant submits that even when combining the cited references not all claim limitations are taught or suggested.

With respect to claim 3 and 13 the Examiner cites Paterson and Brinkman at page 4 section 0059. Applicant respectfully submits that Paterson and Brinkman fail to either disclose or suggest, *inter alia*, a computer-implemented method of validating a computer system. As described herein, these references fail to disclose *validation requirements* for a *computer system*. Brinkman discloses validating a user to use a system, not a computer system. Paterson discloses validating a computer model, not a computer system.

With respect to claims 5 and 15 the Examiner cites Paterson and Brinkman at page 5, section [0071]. Applicant respectfully submits that Paterson and Brinkman do

not disclose any of the listed validation requirements and moreover does not disclose any *validation requirements* for a *computer system*. Brinkman discloses validating a user to use a system not a computer system. Paterson discloses validating a computer model, not a computer system.

With respect to claims 6 and 16 the Examiner cites Paterson and Brinkman at page 9, section [0097]. Applicant respectfully submits that Paterson and Brinkman do not disclose the claim limitation relating to 21 CFR Part 11. Brinkman refers to a National Council for Prescription Drug Programs Telecommunications format - standards for electronic submission of third party drug and/or medical claims. Such standards do not teach or suggest anything related to 21 CFR Part 11.

With respect to claims 7 and 17 the Examiner cites Paterson and Brinkman at page 4, section [0064]. Applicant reiterates its submission with respect to claims 5 and 15, and further respectfully submits that Paterson and Brinkman do not disclose or suggest any qualifications relating to validating a computer system and specifically do not disclose or suggest any of the qualifications of claims 7 and 17. Although Brinkman discloses "a block diagram of the internal hardware of the computer" (Brinkman at page 4, section [0064]), this is simply a system that a user may be validated on and is not related to validation of a computer system, or qualifications therefor.

With respect to claims 8 and 18, and claims 9 and 19, the Examiner cites Paterson and Brinkman at page 7, section [0086]. Applicant reiterates its submission with respect to claims 5 and 15. Further, applicant respectfully submits that Paterson and Brinkman do not disclose or suggest at least an audit relating to validation of a computer system or an audit related to any of the listed qualifications for validating a computer system, as in claims 8 and 18. Brinkman discloses "features such as routine auditing of procedures and processes, random monitoring of a select number of calls..." (Brinkman at page 6, section [0086]). These are related to operation of a system and not validation of a system. Further, and relating in particular to claims 9 and 19,

Brinkman does not disclose, at least, an audit that is "comprised of predefined checklist reflecting best practices applicable to an identifiable type of said system." Again, any audits in Brinkman relate only to operation of the system and not validation, and further do not relate to any predefined checklist.

With respect to claims 10 and 20 the Examiner cites Paterson and Brinkman at page 7, section [0085]. Applicant respectfully submits that neither Paterson nor Brinkman disclose or suggest at least a report that "indicates that said requirements are not achieved unless an affirmative response that each requirement [for validating a computer system] was achieved has been received."

Reports in Brinkman are not related to validating a computer system - they relate to follow-up items after a call with a patient (Brinkman at page 7, section [0083]), utilization reports relating to, for example, call times (Brinkman at page 7, section [0084]), and advertising opportunities (Brinkman at page 7, section [0085]). Not only do these reports not relate to validating a computer system, they don't relate to validation of users of a system, the only validation in Brinkman.

Reports in Paterson do not relate to validating a computer system as Paterson does not relate to validating a computer system. Further, any reports in Paterson are not influenced by receiving an affirmative response. As described with respect to Figure 12 in Paterson and further describe herein with respect to claim 1, the results of stimulus-response tests may be presented to the user and may be compared to expected results. Presentation of the results does not require receiving an affirmative response, and does not institute a report for a validation requirement for a computer system.

With respect to claim 23 the Examiner cites Paterson and Brinkman at page 7, sections [0089 - 0091]. Applicant respectfully submits that neither Paterson nor Brinkman disclose or suggest at least "generating a unique user code respective to said

user provided said user successfully completes said training session". The Applicant re-iterates its submissions from its previous office action response filed 07 May 2007. Neither Brinkman nor Paterson disclose or suggest a "training session". Further, Brinkman, does not provide a user code after successful completion of a training session, or after hearing options that are provided by the system as in Brinkman. Applicant refers, as an example, to page 7 section [0090] where a user must already have a user code to access the system and to page 7 section [0091] where a user can by-pass this requirement and talk to an operator. At no point in Brinkman is a unique user code generated provided a user successfully completes a training session.
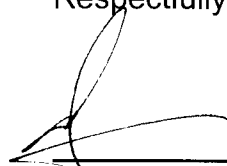
CONCLUSION

Applicant believes that it has fully responded to the Examiner's concerns, and that the claims are in condition for immediate allowance. Applicant respectfully requests reconsideration and immediate allowance of the claims.

Applicant requests that any questions concerning this matter be directed to the undersigned at (416) 865-8242.

Respectfully submitted,

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